

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE SUBOXONE (BUPRENORPHINE  
HYDROCHLORIDE AND NALOXONE)  
ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

*Wisconsin, et. al. v. Indivior Inc. et. al.*

MDL No. 2445

Master File No. 2:13-MD-2445-MSG

Case No. 2:16-cv-5073-MSG

STATE OF WISCONSIN et. al.

Plaintiffs,

v.

Indivior Inc. f/k/a Reckitt Benckiser  
Pharmaceuticals, Inc., et. al.

Defendants.

Civ. A. No. 16-cv-5073

**MEMORANDUM OF LAW IN OPPOSITION  
TO DEFENDANT INDIVIOR INC.'S  
MOTION TO DISMISS**

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## INTRODUCTION

Defendant Indivior Inc. (“Indivior”) has moved this Court for an order dismissing the Plaintiff States’ First Amended Complaint (“FAC”). The States’ FAC is not drawn on a blank slate; this action is factually related to other similar suits against Indivior.<sup>1</sup> Although this Court has already twice ruled on—and denied—Indivior’s motions to dismiss the claims asserted in those actions,<sup>2</sup> Indivior yet again seeks dismissal. In support of its motion, Indivior attacks the merits of the States’ allegations as if discovery and trial were concluded. In doing so, Indivior attempts to dodge the standard by which motions to dismiss are to be adjudicated.

Each of Indivior’s arguments for dismissal is without merit. Its reliance on the Third Circuit’s recent decision regarding the drug Doryx<sup>3</sup> is misplaced. *Doryx* did not alter the pleading standards or legal requirements for antitrust claims, and like the complaints of the Class Plaintiffs and Amneal before it, the FAC contains specific factual allegations of Indivior’s anticompetitive scheme and effects as required under Rule 12(b)(6). Any procompetitive justifications for Indivior’s conduct do not preclude liability, and can only be assessed after the factual development of the record and a rule of reason analysis.

Contrary to Indivior’s argument, variation among the States’ substitution laws has no effect on the application of the Sherman Act. Nor do the States rely solely on the substitution laws in order to state their claim. To the contrary, the FAC factually describes a series of actions which, taken together, clearly allege a scheme of anticompetitive conduct designed to have

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<sup>1</sup> *In re Suboxone Antitrust Litig.*, Civ. A. No. 2:13-md-2445-MSG.

<sup>2</sup> Memorandum Opinion dated Dec. 3, 2014 in *In re Suboxone Antitrust Litig.*, Civ. A. No. 2:13-md-2445, 64 F. Supp. 3d 665 (E.D. Pa. 2014) (ECF Dkt. No. 97) (granting in part and denying in part Indivior’s motions to dismiss class plaintiffs’ claims) (hereinafter, “Class Plaintiffs Opinion”); Order on Defendants’ Local Civil Rule 7.1(g) Motion to Reconsider, dated Apr. 14, 2015 in *In re Suboxone Antitrust Litig.*, Civ. A. No. 2:13-md-2445, 2015 WL 12910728 (E.D. Pa. 2015) (ECF Dkt. No. 152) (hereinafter, “Reconsideration Order”); Memorandum Opinion dated Jan. 4, 2017 in *In re Suboxone Antitrust Litig.*, Civ. A. No. 2:13-md-2445, 2017 WL 36371 (E.D. Pa. Jan. 4, 2017) (ECF Dkt. No. 311) (granting in part and denying in part Indivior’s partial motion to dismiss Amneal Pharmaceuticals LLC’s (“Amneal”) claims) (hereinafter, “Amneal Opinion”).

<sup>3</sup> *Mylan Pharm. Inc. v. Warner Chilcott Public Ltd.*, 838 F.3d 421 (3d Cir. 2016) (“*Doryx*”).



anticompetitive effects. Included among those actions are Indivior's delay tactics through the abuse of the REMS process and the citizen petition. This Court has already rejected Indivior's opinion that such conduct is not actionable,<sup>4</sup> and nothing in the States' FAC nor Indivior's memorandum justifies a departure from the previous rulings.

Legally, Indivior and co-defendant MonoSol RX, LLC ("MonoSol") were capable of forming the conspiracy which they carried to fruition. Their goal of stifling generic competition in the market for co-formulated buprenorphine/naloxone was met, as is properly alleged in the FAC. Taken as a whole, not piecemeal as Indivior argues in its memorandum, the facts alleged clearly establish claims that entitle the Plaintiff States to relief.

## **LAW AND ARGUMENT**

### **I. Legal Standard**

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'"<sup>5</sup> To determine the sufficiency of a complaint, a court should: (1) "tak[e] note of the elements a plaintiff must plead to state a claim;" (2) identify the allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth;" and (3) "where there are well-pleaded factual allegations, ... assume their veracity and then determine whether they plausibly give rise to an entitlement for relief."<sup>6</sup>

The arguments set forth by Indivior in its Motion to Dismiss cannot change reality: Plaintiff States have set forth factual allegations that—taken as a whole and accepted as true—

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<sup>4</sup> See Class Plaintiffs Opinion, ECF Dkt. No. 97, Reconsideration Order, ECF Dkt. No. 152, and Amneal Opinion, ECF Dkt. No. 311.

<sup>5</sup> *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

<sup>6</sup> *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) (citations omitted).

render plausible their claims to relief against Indivior under Sections 1 and 2 of the Sherman Act, and its Motion to Dismiss therefore must be denied.

## **II. Legal Elements of the Claims and Plaintiffs' Factual Allegations in Support**

As set forth in the FAC, Defendant Indivior has committed three violations of 15 U.S.C. § 2: (1) monopolization, (2) attempted monopolization, and (3) conspiracy to monopolize. Indivior also illegally restrained trade in violation of 15 U.S.C. § 1. While some elements of these four claims overlap, each distinct claim requires that certain factors be alleged.

### **A. Plaintiffs state a claim for monopolization under Section 2 of the Sherman Act.**

Indivior violated Section 2 of the Sherman Act because (1) it possessed monopoly power in a relevant market; and (2) it willfully acquired, maintained and used that power by anticompetitive or exclusionary means as opposed to “growth or development resulting from a superior product, business acumen, or historic accident.”<sup>7</sup>

Even a monopolist who has gained monopoly power through lawful means (such as a patent holder) is not entitled to engage in anticompetitive conduct.<sup>8</sup> Conduct is considered “anticompetitive” when it has no legitimate business purpose and “makes sense only because it eliminates competition.”<sup>9</sup> Anticompetitive conduct can also be identified as conduct that takes place when a monopolist “competes on some basis other than the merits.”<sup>10</sup> Courts have repeatedly stated that a determination of what constitutes anticompetitive conduct must be made on a case-by-case basis through a “thorough analysis of each fact situation.”<sup>11</sup> This is due, in part, to the fact that “anticompetitive conduct can come in too many different forms, and is too

<sup>7</sup> *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 595-96 (1985) (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).

<sup>8</sup> *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

<sup>9</sup> *LePage's Inc. v. 3M*, 324 F.3d 141, 153-54 (3d Cir. 2003).

<sup>10</sup> *LePage's*, 324 F.3d at 147 (citing *Aspen Skiing Co.*, 472 U.S. at 605).

<sup>11</sup> *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 782 (6th Cir. 2002) (citing *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 467 (1992)).

dependent upon context, for any court or commentator ever to have enumerated all the varieties.”<sup>12</sup> Plaintiff States are not required to show that Indivior’s acts were “of a kind that would be unlawful for an ordinary enterprise.”<sup>13</sup> Rather, they need show only that the monopolist’s actions “unnecessarily excluded competition.”<sup>14</sup> Simply put, when a monopolist like Indivior chooses not to compete with another firm on the merits, instead opting to prevent that firm from even *becoming* competition in the marketplace, it has violated Section 2.

The FAC thoroughly sets forth the predicate factual bases of a Section 2 monopolization claim against Indivior. Monopoly power in a relevant market is alleged,<sup>15</sup> as is Indivior’s scheme aimed at eliminating—not competing with—generic competition. Plaintiffs describe, in detail, how Indivior launched its “Buprenorphine Generic Offensive Strategy” aimed at protecting Indivior’s monopoly revenues by stifling the generic competition it knew Suboxone would soon face.<sup>16</sup> Indivior developed a new formulation of Suboxone with patent protection and no generic competition, and ensured that its new formulation would not be an AB-rated substitute with any generic versions of the prior Suboxone formulation.<sup>17</sup> Indivior then engaged in a multi-faceted campaign to switch the entire Suboxone market from its old Tablet formulation to the new Film formulation, ultimately withdrawing the Tablet formulation from the market to ensure that any would-be generic competitors would have no branded equivalent and thus could not benefit from AB-rated generic substitution.<sup>18</sup>

Indivior committed many other anticompetitive acts while product hopping from Tablets to Film. As part of its campaign to convince providers to switch patient prescriptions to the new

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<sup>12</sup> *LePage’s*, 324 F.3d at 152 (internal citations omitted).

<sup>13</sup> *California Comput. Prod., Inc. v. Int’l Bus. Mach. Corp.*, 613 F.2d 727, 735 (9th Cir. 1979) (internal citations omitted).

<sup>14</sup> *Ca. Comp. Prod., Inc.*, 613 F.2d at 735.

<sup>15</sup> FAC ¶¶ 19-22.

<sup>16</sup> *Id.* ¶¶ 39-45.

<sup>17</sup> *Id.* ¶¶ 46-60.

<sup>18</sup> *Id.* ¶¶ 69-88.

product, Indivior falsely disparaged the Tablet formulation by raising unfounded safety concerns.<sup>19</sup> It also engaged in tactics meant to delay FDA approval of generic entrants, including filing a sham citizen petition<sup>20</sup> and feigning cooperation with the generic manufacturers on a “shared REMS” (Risk Evaluation and Mitigation Strategy) plan required by the FDA, enabling Indivior to actually exert control and intentionally slow down the REMS process.<sup>21</sup>

The FAC describes Indivior’s anticompetitive conduct as a series of acts which, taken together, effectively eliminated competition. This Court recently held that similar allegations were sufficient to state Sherman Act claims against Indivior, stating in the Amneal Opinion: “a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable.”<sup>22</sup> The Supreme Court itself has expressly cautioned against analyzing a series of facts in an antitrust case as if they were “completely separate and unrelated lawsuits,” stating that “plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various components and wiping the slate clean after scrutiny of each,”<sup>23</sup> an approach echoed by the Third Circuit: “the relevant inquiry is the anticompetitive effect of [defendant’s] exclusionary practices considered together...courts must look to the monopolist’s conduct taken as a whole rather than considering each aspect in isolation.”<sup>24</sup> The Third Circuit further encouraged trial courts to look at the whole picture and consider each alleged action’s “overall combined effect.”<sup>25</sup>

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<sup>19</sup> *Id.* ¶¶ 57-68, 72-82.

<sup>20</sup> *Id.* ¶¶ 98-111.

<sup>21</sup> *Id.* ¶¶ 89-97.

<sup>22</sup> Amneal Opinion at 16 (citing *Continental Ore Co. v. Union Carbide*, 370 U.S. 690, 699 (1962)); *LePage’s*, 324 F.3d at 162; *In re Gabapentin Patent Litig.*, 649 F.Supp. 2d 340, 359 (D.N.J. 2009); *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at \*15 (D.N.J. Aug. 28, 2009); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F.Supp. 2d 408, 428 (D.Del. 2006)).

<sup>23</sup> *Continental Ore Co.*, 370 U.S. at 698-99.

<sup>24</sup> *LePage’s*, 324 F.3d at 162.

<sup>25</sup> *Id.*

**B. Plaintiffs state an attempted monopolization claim under Section 2 of the Sherman Act.**

Indivior also attempted to monopolize in violation of Section 2, because it (1) had specific intent to monopolize, and (2) engaged in anticompetitive conduct that, taken as a whole, (3) created a dangerous probability of achieving monopoly power.<sup>26</sup>

The FAC alleges a number of facts showing that Indivior “intended to achieve an illegal monopoly.”<sup>27</sup> Plaintiffs need not “establish specific intent with ‘smoking gun’ documents that articulate antitrust scienter in no uncertain terms.”<sup>28</sup> Rather, specific intent “may be inferred from a defendant’s unlawful conduct.”<sup>29</sup> The Plaintiff States have alleged a number of facts that demonstrate Indivior’s specific intent to monopolize the market for co-formulated buprenorphine/naloxone, describing statements by Indivior regarding its desire to develop new formulations of Suboxone specifically to defeat generic competition, Indivior’s partnership with MonoSol (a firm specifically marketing itself as a resource to beat patent “cliffs”), evidence that Indivior brought Suboxone Film to market to avoid competition from generic entrants, and many more.<sup>30</sup>

Indivior’s anticompetitive conduct has been addressed in connection with the Count I monopolization claim, and is likewise sufficiently alleged for purposes of the Count II attempted monopolization claim. Lastly, Plaintiff States have alleged facts which not only demonstrate a “dangerous probability of success,” but establish Indivior’s successful monopolization of the subject market as evidenced by its retention of market share after the introduction of generic

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<sup>26</sup>*West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 108 (citing *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 454-58 (1993)).

<sup>27</sup>*Howard Hess Dental Labs, Inc. v. Dentsply Int’l, Inc.*, 602 F.3d 237, 257 (3d Cir. 2010) (internal citations omitted).

<sup>28</sup>*Advo, Inc. v. Philadelphia Newspapers, Inc.*, 51 F.3d 1191, 1199 (3d Cir. 1995).

<sup>29</sup>*Dentsply*, 602 F.3d at 257 (citing *Advo*, 51 F.3d at 1199).

<sup>30</sup>See FAC ¶¶ 42, 44, 48, 63, 69, 70, 73, 77, 81, 83, 86, 93-95, 102-103, 106-107.

competition.<sup>31</sup> Thus, the FAC sufficiently alleges a claim against Indivior for attempted monopolization under Section 2 of the Sherman Act.

**C. Plaintiffs state a conspiracy to monopolize claim under Section 2 of the Sherman Act.**

Indivior also conspired to monopolize in violation of Section 2. The FAC adequately sets forth facts demonstrating (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged.<sup>32</sup>

“An agreement exists when there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme.”<sup>33</sup> Such agreement may be shown by direct or circumstantial evidence or a combination thereof, but “[i]f a complaint includes non-conclusory allegations of direct evidence of an agreement, a court need go no further on the question whether an agreement has been adequately pled.”<sup>34</sup> The FAC compellingly alleges an illegal agreement between Indivior and Defendant MonoSol to monopolize the market for co-formulated buprenorphine/naloxone. It details meetings between the two parties for the express purpose of developing that monopolization scheme, as well as the actual contractual and legal relationships between the entities to bring the scheme to fruition.<sup>35</sup> Likewise, Plaintiffs allege with specificity a number of acts taken in furtherance of the conspiracy by both parties in concert, including communications and meetings that discussed filing the sham citizen petition, speeding the approval process for Suboxone Film in order to beat

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<sup>31</sup> See *Id.* ¶¶ 22, 87.

<sup>32</sup> *Dentsply*, 602 F.3d at 252 (citing *United States v. Yellow Cab Co.*, 332 U.S. 218, 224-25 (1947); *Am. Tobacco Co., v. United States*, 328 U.S. 781, 788, 809, (1946)).

<sup>33</sup> *W. Penn Allegheny Health Sys.*, 627 F.3d at 99 (citing *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 771 (1984)).

<sup>34</sup> *Id.*

<sup>35</sup> FAC ¶¶ 46-54.

the entry of generic tablets, and most significantly, removing the branded Tablets from the market in order to prevent generic substitutability.<sup>36</sup>

The element of specific intent is sufficiently alleged in the FAC,<sup>37</sup> as demonstrated through the discussion on Plaintiffs' attempt to monopolize claim. The causal connection is sufficiently alleged in the FAC as well.<sup>38</sup>

**D. Plaintiffs state a conspiracy in restraint of trade claim under Section 1 of the Sherman Act.**

In addition to its actions in violation of Section 2, Indivior also conspired to restrain trade in violation of Section 1. The FAC sets forth, in great detail, facts demonstrating (1) concerted action by defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that consumers were injured as a proximate result of the concerted action.<sup>39</sup>

Actions are illegal under Section 1 when they unreasonably restrain trade.<sup>40</sup> Under a "rule of reason" analysis, whether actions unreasonably restrain trade must be examined through an extremely factual, case-by-case analysis,<sup>41</sup> requiring factfinders to "weigh all circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition."<sup>42</sup> Unreasonable restraints are limited to those that suppress competition rather than promote it.<sup>43</sup>

The rule of reason analysis is structured as a burden-shifting framework. First, the plaintiff bears the burden of proving that an agreement has had, or is likely to have, a

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<sup>36</sup> *Id.* ¶¶ 46-54, 61, 71, 85.

<sup>37</sup> *Id.* ¶¶ 42, 44, 48, 63, 69, 70, 73, 77, 81, 83, 86, 93-95, 102-103, 106-107.

<sup>38</sup> *Id.* ¶¶ 17, 22, 25, 96-97, 111-115, 116-126.

<sup>39</sup> *Dentsply* 602 F.3d at 252 (citing *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 207 (3d Cir. 2005)).

<sup>40</sup> *W. Penn. Allegheny* 627 F.3d at 99.

<sup>41</sup> *Id.* (citing *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, (2007)).

<sup>42</sup> *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

<sup>43</sup> *National Soc'y of Prof'l Engineers v. United States*, 435 U.S. 679, 688 (1978).

substantially adverse effect on competition. The defendant may then offer evidence that the action has procompetitive benefits. The burden then shifts back to the plaintiff to show that any alleged benefits are pretextual, or are outweighed by anticompetitive effects.<sup>44</sup> This burden-shifting analysis is also used to determine whether conduct is anticompetitive under Section 2 claims.<sup>45</sup> Plaintiffs have adequately alleged that Indivior's actions unreasonably restrained trade through the same factual allegations that established anticompetitive conduct under Section 2.

The FAC also clearly alleges anticompetitive effects flowing from Indivior's actions. Effects are considered anticompetitive when they "lessen competition, rather than merely disadvantage rivals."<sup>46</sup> The FAC plainly alleges that Indivior's conduct not only caused delays to the entry of generic competitors, but also effectively destroyed the market for those generic entrants once they did finally enter, thus drastically limiting competition.<sup>47</sup>

Finally, the FAC satisfactorily alleges injury as a proximate cause of Indivior's illegal scheme.<sup>48</sup> The "existence of antitrust injury is not typically resolved through motions to dismiss," and if plaintiffs allege that an antitrust injury has been suffered, as the Plaintiff States do here, the complaint should not be dismissed.<sup>49</sup> Plaintiffs are not required to prove direct injury from each of a defendant's anticompetitive acts. Nor must plaintiffs allege that the defendant's conduct was the *sole* cause of injury. Instead, a determination should rely upon whether the plaintiff was injured by the anticompetitive conduct as a whole.<sup>50</sup> With their

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<sup>44</sup> *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1367-68 (3d Cir. 1996).

<sup>45</sup> *United States v. Microsoft*, 253 F.3d 34 (D. D.C. 2001).

<sup>46</sup> *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016).

<sup>47</sup> FAC ¶¶ 116-123.

<sup>48</sup> *Id.* ¶¶ 124-129.

<sup>49</sup> *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686 (E.D. Pa. 2004) (citing *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417-19 (3d Cir. 1997); *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998)).

<sup>50</sup> *In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at \*11 (citing *Biovail Corp. Int'l v. Hoechst AG*, 49 F. Supp. 2d 750, 767 (D.N.J. 1999); *Apotex Corp.*, 383 F. Supp. 2d at 702; *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 (1969)).



standing to seek injunctive relief and disgorgement in a *parens patriae* capacity for harm to the “general economy,”<sup>51</sup> the States’ FAC plainly alleges antitrust injury through its description of Indivior’s anticompetitive scheme and the harm it caused to the marketplace and economy of each state in which it occurred.

### **III. Indivior’s Arguments are Incorrect and Unpersuasive**

#### **A. *Doryx* does not preclude Plaintiff States’ claims, nor add new requirements that have not been pled.**

Ignoring that Plaintiffs have clearly pled facts supporting each of their claims, Indivior relies heavily on the Third Circuit’s recent decision in *Doryx*.<sup>52</sup> Citing “foreclosure” and “price disconnect” without any contextual reference to the actual requirements of Sherman Act claims, Indivior’s attempts to muddy the waters regarding the legal elements of an antitrust claim are unconvincing and cannot change the conclusion that Plaintiff States have sufficiently alleged all necessary elements of their claims.

#### **1. The *Doryx* opinion is legally and factually distinguishable from Suboxone and is not dispositive of the States’ claims.**

Contrary to Indivior’s arguments, *Doryx* manifestly does not stand for the proposition that product-hop cases cannot be successful, or that some formulaic particularity is necessary for the successful assertion of a Sherman Act claim with a product-hop component. On the contrary, the court recognized that a product-hop could be a part of a course of conduct giving rise to anticompetitive effects, stating: “To be clear, we do not rule out the possibility that certain insignificant redesign or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases.”<sup>53</sup>

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<sup>51</sup> *Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 264 (1972).

<sup>52</sup> *Mylan Pharm. Inc. v. Warner Chilcott Public Ltd.*, 838 F.3d 421 (3d Cir. 2016) (“*Doryx*”).

<sup>53</sup> *Id.* at 440.

Endorsing the use of the *Microsoft* burden-shifting framework in product-hop cases, the Third Circuit cautioned courts to carefully consider the “unique separation between consumers and drug manufacturers” in the pharmaceutical market, “especially in cases where there is evidence of extreme coercion of physician prescribing decisions or blatant misrepresentations about a generic manufacturer’s version of a drug.”<sup>54</sup> It also noted that “a so-called ‘patent cliff’ is indicative of anticompetitive conduct, especially when a defendant’s actions are paired with weak or inconsistent evidence of procompetitive justifications.”<sup>55</sup>

From the *Doryx* court’s own language, the factual distinctions between it and Suboxone are readily apparent. Here, the FAC clearly alleges coercion of physician-prescribing decisions, as well as misrepresentations about generic versions of Suboxone. And, importantly, Indivior faced a “patent cliff” as it planned and executed its anticompetitive scheme.

The distinctions between the cases do not end there. In *Doryx*, the court determined that the defendant did not possess monopoly power in the relevant market (all oral tetracyclines prescribed to treat acne) because the defendant possessed only about an 18% market share. The court defined the relevant market after extensive evidence, both from prescribers regarding interchangeability and from experts regarding the cross-price elasticity of demand. Thus, plaintiffs could not sustain a monopolization claim under Section 2.<sup>56</sup> Ultimately, the *Doryx* court determined that the remainder of the plaintiff’s claim relied entirely on defendant’s product hop, which produced no anticompetitive effects because generic competition (including plaintiff Mylan) was not foreclosed from its more broadly-defined market. It noted that the “hop” activity had taken place over an extremely extended timeframe (“Doryx capsules were available for more than twenty years, and generic companies were free to engineer their own versions during that

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<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 436-437.

time”), and that other companies had introduced generic competition.<sup>57</sup> The court specifically contrasted the time frame with the “patent cliff” faced by the defendant in *Namenda*.<sup>58</sup>

Specifically observing the differences in procedural posture of not only *Namenda* but also of *Suboxone* itself, the Third Circuit commented that the *Doryx* plaintiff had also survived the motion-to-dismiss stage and been allowed to fully develop its case, and had “proceeded through full discovery and resulted in a robust record void of any evidence of anticompetitive conduct.”<sup>59</sup> Accordingly, *Doryx* is unpersuasive when considering whether the FAC states a claim for relief.

**2. “Foreclosure” is not a magic word and Plaintiff States have sufficiently alleged anticompetitive conduct and anticompetitive effects.**

Indivior argues that “foreclosure is a necessary element of a product-hop claim”<sup>60</sup> that Plaintiff States have failed to allege.<sup>61</sup> Market foreclosure is simply a method to show anticompetitive conduct and anticompetitive effects. Plaintiffs, however, are not required to use any particular phrase, including “foreclosure,” to state a claim, and have sufficiently pled anticompetitive conduct and effects under Rule 12(b)(6).<sup>62</sup>

While “one competitor’s inability to compete” (such as Mylan alleged in *Doryx*) “does not automatically mean competition has been foreclosed,”<sup>63</sup> it is also the case that total foreclosure of any and all competitors is not required. Rather, the “challenged practices must ‘bar a substantial number of rivals or severely restrict the market’s ambit’”<sup>64</sup> or even foreclose

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<sup>57</sup> *Doryx*, 838 F.3d at 438.

<sup>58</sup> *Id.* at 439 (distinguishing *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (“*Namenda*”).

<sup>59</sup> *Doryx*, 838 F.3d at 440.

<sup>60</sup> Memorandum in Support of Indivior Inc.’s Motion to Dismiss (“Ind. Br.”) at p. 7.

<sup>61</sup> Ind. Br. at p. 7, 9-11.

<sup>62</sup> Class Plaintiffs Opinion at 33 (“To dismiss a claim for not using that exact language would be to place form over substance.”)

<sup>63</sup> *Eisai*, 821 F.3d at 404

<sup>64</sup> *Id.* at 403 (quoting *Dentsply*, 602 F.3d at 191).

only “one significant competitor.”<sup>65</sup> A market foreclosure analysis looks to what products are *reasonably* available to a consumer, and recognizes that “a monopolist ‘may use its power to break the competitive mechanism and deprive customers of the ability to make a meaningful choice.’”<sup>66</sup> “Substantial foreclosure allows the dominant firm to prevent potential rivals from ever reaching ‘the critical level necessary’ to pose a real threat to the defendant’s business.”<sup>67</sup>

Plaintiff States have sufficiently made precisely these allegations,<sup>68</sup> and any assertion that the use of the word “foreclosure” is necessary is simply an attempt by Indivior to place form over substance.

**3. There is no requirement that an antitrust plaintiff must specifically allege “price disconnect” in pharmaceutical cases.**

In addition to asserting a false “total foreclosure” theory, Indivior attempts to infuse another magic phrase, “price disconnect,” into the elements of Sherman Act claims.<sup>69</sup> There is no such pleading requirement. The FAC amply alleges anticompetitive conduct and effects, which is sufficient to state a claim under the Sherman Act.

Price disconnect is but one of the peculiarities of the pharmaceutical market that give rise to anticompetitive effects not otherwise present in a typical market. As described by the court in *Namenda*:

Hatch-Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. In a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, however, the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug. The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health

<sup>65</sup> *LePage’s*, 324 F.3d at 159 (citing *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 394 (7th Cir. 1984)).

<sup>66</sup> *Eisai*, 821 F.3d at 403-404 (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 285 (3d Cir. 2012)).

<sup>67</sup> *ZF Meritor*, 696 F.3d at 286 (quoting *Dentsply*, 602 F.3d at 191).

<sup>68</sup> FAC ¶¶ 17, 22, 25, 96-97, 111-115, 116-126.

<sup>69</sup> Ind. Br. at 10.

insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account...The basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescription.<sup>70</sup>

*Namenda* then explained how state substitution laws are “designed to correct for this price disconnect by shifting drug selection...from doctors to pharmacists and patients, who have greater financial incentives to make price comparisons.”<sup>71</sup> Plaintiffs address this function of the state substitution laws, which are meant to effectively correct for price disconnect, within the FAC. Any separate specific allegation regarding price disconnect is unnecessary, as Plaintiff States have pled many facts regarding the operation of the pharmaceutical market—including the function of the Hatch-Waxman Act, AB-rated generic substitutability, and state substitution laws—which adequately allege anticompetitive conduct and anticompetitive effects.<sup>72</sup>

None of the Plaintiffs’ statements in the FAC regarding Indivior’s pricing of Suboxone negatively impact their allegations of anticompetitive effects, nor do they erase or ignore the fact that price disconnect actually exists in the pharmaceutical market. Plaintiffs allege that Indivior raised the price of Suboxone Tablets and lowered the price of the Film as part of their campaign to induce participants at every level of the pharmaceutical industry—prescribers, payors, pharmacists and consumers—to switch from Tablets to Film. Thus, at least for a period, the notion of “price disconnect” was not even necessary to explain the operation of the market for Suboxone. There were two branded choices: the old Tablets or the new Film. No generic substitutes existed for either product. In order to incentivize all decision-makers in the pharmaceutical industry to switch from the old product to the new, Indivior knew it had to make

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<sup>70</sup> *Namenda*, 787 F.3d at 645-646 (internal quotations omitted).

<sup>71</sup> *Id.* at 646.

<sup>72</sup> FAC ¶¶ 20, 22, 26-32, 40-41, 55-56, 115-129.

the new Suboxone Film attractive to payors. Thus, along with falsely disparaging the Tablet (and thus its would-be generic competition) as “unsafe,” Indivior engaged in the described pricing campaign to make the Film marketable to payors.

None of those allegations undermine the anticompetitive effects of Indivior’s behavior or of the function of “price disconnect” in the pharmaceutical industry. To the contrary, the pricing allegations reinforce the anticompetitive nature of Indivior’s conduct, which was intended to eliminate competition and had no other legitimate business purpose.

**4. Plaintiff States do not rely solely upon state substitution laws to state Sherman Act claims.**

Indivior incorrectly argues that the States are “relying entirely” on state substitution laws to allege foreclosure.<sup>73</sup> Not only is that argument inaccurate, it also ignores Indivior’s entire anticompetitive scheme as alleged in the FAC, upon which Plaintiff States *actually* rely.

A product-hop claim is simply an allegation of a certain type of anticompetitive conduct, and the sufficiency of any such claim should be analyzed just as any other anticompetitive conduct—by questioning whether it eliminates competition. In a “typical market,” consumers exercise choice among products in a marketplace based on their merits, creating competition between a new product and an older version. In contrast, the nature of the pharmaceutical market restricts this “typical” type of choice.

Moreover, if a monopolist removes the older version of a product, any choice a consumer *could* exercise is lost. This gives rise to precisely the type of anticompetitive effects contemplated by the Sherman Act—the *reduction* of competition in the market.<sup>74</sup> Potential competitors “need not be barred ‘from all means of distribution’ if they are barred ‘from the cost-

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<sup>73</sup> Ind. Br. at 12-13.

<sup>74</sup> See *Abbott Labs v. Teva Pharms. USA, Inc.*, 432 F.Supp. 2d 408, 423 (D. Del. 2006).

efficient ones.’”<sup>75</sup> Numerous courts have held that the states’ generic substitution laws are the most cost-efficient means of competition for generic drugs, and that a monopolist’s product hop can constitute an anticompetitive act by “gaming” the “rather intricate” FDA rules.<sup>76</sup>

Unlike the plaintiff in *Doryx*, however, the States do not rest their entire claim on allegations of a product hop and market foreclosure pursuant to state substitution laws. Here, the Plaintiffs have alleged the “something more” contemplated in the *Doryx* opinion, including the ample allegations of coercion regarding physician prescribing decisions, and misrepresentations about a generic competitor’s version of a drug as specifically identified by the *Doryx* court.<sup>77</sup> In particular, the FAC describes Indivior’s substantial coercive measures, including making unfounded safety concerns regarding the Tablet formulation, filing a sham citizen petition, and the threat and subsequent removal of its Tablet from the market.<sup>78</sup> Additionally, the would-be generic competitors to Suboxone did not have a twenty-year time period in which to formulate and market their generic substitutes as the plaintiff did in *Doryx*. Consequently, the state substitution laws had a more significant impact on Suboxone generics than they might have had in *Doryx*.

#### **B. State substitution laws have no bearing on the application of the Sherman Act.**

Citing *Mississippi Band of Choctaw Indians v. Holyfield*,<sup>79</sup> Indivior states that the Sherman Act must be interpreted to have “uniform nationwide application.” It argues that by alleging anticompetitive effects flowing from the operation of state substitution laws, the Plaintiffs have “doomed” their Sherman Act claims because the various state’s substitution laws are not identical. This argument is simply wrong. The “uniform nationwide application”

<sup>75</sup> *Id.* at 423 (citing *Microsoft*, 254 F.3d at 64).

<sup>76</sup> See *Abbott Labs*, 432 F. Supp. 2d at 422; *Namenda*, 787 F.3d 638.

<sup>77</sup> *Doryx*, 838 F.3d at 440.

<sup>78</sup> FAC ¶¶ 65-68, 70-71, 73-78, 81-82, 102-111.

<sup>79</sup> 490 U.S. 30 (1989).

quotation from *Mississippi Band of Choctaw Indians* was applied to the interpretation of exclusive jurisdiction under the Indian Child Welfare Act over adoptions involving domiciliaries of reservations. In addressing the different ways “domicile” may be defined under state laws, the court ruled that the application of federal acts cannot be *dependent* upon state law.

Here, in contrast, state substitution laws have no control over the application of the Sherman Act. The Sherman Act applies uniformly across all states, just as it always has. The only effect of variations in the state substitution laws is a potential impact in the ability of a plaintiff to show antitrust injury, a necessary element under certain Sherman Act claims.<sup>80</sup> Those differences would not, however, affect the *applicability* of the Sherman Act so as to make the Act’s application “*dependent* upon state law.” Moreover, since Plaintiff States have plausibly alleged antitrust injury in the FAC by alleging harm to the marketplace and to the economy of each state, and since the ultimate determination of injury is a fact-specific inquiry dependent upon discovery, Indivior’s argument provides no basis for a motion to dismiss.<sup>81</sup>

### **C. Indivior can and did conspire with MonoSol as a matter of law.**

Arguing that Plaintiffs have not properly alleged a conspiracy or concerted action, Indivior makes the absurd leap that it is legally incapable of conspiring with MonoSol because the two had a “unity of economic interest and design.”<sup>82</sup> To the contrary, a “unity of interest” is

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<sup>80</sup> Indivior is not only legally wrong in its claims regarding the effect of state substitution laws, but is also wrong on many of the facts related to state substitution laws. For illustrative purposes only and without waiving any defenses of various states, Plaintiffs identify the following statutes and misrepresentations by Indivior: Conn. Gen. Stat. § 20-619(a)(5) & (b) (substitution is not permitted because different dosage forms contrary to Ind. Br. at 13); Minn. Stat. Section 151.21 sub.3 & Minn. R. 9505.0340 subpart 3(H) (substitution permitted only if drug is generically and therapeutically equivalent in pharmacist’s professional opinion and only for Medicaid patients if drug is deemed therapeutically equivalent by FDA, contrary to Ind. Br. at 13); Okla. Admin. Code 317:30-5-76 & 77 (substitution permitted by pharmacist with patient consent; substitution required under Medicaid, contrary to Ind. Br. at 14); W.Va. Code § 60A-3-308(e) (repealed and only in effect for a brief time in contrast to Ind. Br. at 14); S.C. Code § 39-24-20(3) (substitution permitted contrary to Ind. Br. at 14); Washington statute cited in Ind. Br. at 13 not applicable due to pricing of Film.

<sup>81</sup> See *Namenda*, 787 F.3d at 662 (rejecting similar arguments)

<sup>82</sup> Ind. Br. at 15.



precisely how the case law analyzing antitrust conspiracies *defines* a conspiracy.<sup>83</sup> To hold that a shared “unity of interest” renders two entities legally incapable of forming a conspiracy would be to swallow the purpose of conspiracy under the Sherman Act whole. Every conspiracy necessarily shares a “unity of interest”—that interest which is the goal of the conspiracy.

Indivior’s argument is contrary to well-established precedent. Indivior claims that *Copperweld* and *Siegel Transfer* stand for the proposition that a conspiracy cannot take place unless the parties have “independent competitive interests in the alleged market.”<sup>84</sup> In *Copperweld*, however, the court stated: “We limit our holding to the narrow issue squarely presented: whether a parent and its wholly-owned subsidiary are capable of conspiring in violation of Section 1 of the Sherman Act,” adding that it did not consider any other circumstances or relationships.<sup>85</sup> As Indivior and MonoSol have no such parent-subsidiary relationship, the narrow holding of *Copperweld* has no bearing on the ability of the two to conspire.

*Siegel* also does not support the idea that conspiracy defendants must have an “independent market presence.” In *Siegel* the court analyzed the relationships of entities far more closely-related than any relationship that Indivior has alleged with respect to MonoSol. Those defendants consisted of companies within a corporate family and their agents. Ownership of certain entities was near complete, akin to a parent-subsidiary relationship, and others were so intertwined that they were considered to be a single enterprise and an inseparable part of one another’s structure. No such allegations have been made regarding Indivior and MonoSol, and if Indivior intends to analogize the two companies in that manner, then discovery is appropriate to

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<sup>83</sup> *Copperweld*, 467 U.S. at 771, *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir. 2010); *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 (3d Cir. 2004).

<sup>84</sup> Ind. Br. at 16.

<sup>85</sup> *Copperweld*, 467 U.S. at 767.

explore the factual background of the corporate relationships. (*Siegel* was decided on a motion for summary judgment following opportunity for significant discovery regarding the entities' relationships.)

Indivior further argues that royalties paid to MonoSol tie MonoSol's well-being to Indivior in a manner that gives rise to a "single entity" incapable of conspiring. This argument is unpersuasive. The *Siegel* court relied heavily on the Eighth Circuit case *Pink Supply Corp.* in its decision.<sup>86</sup> In *Pink Supply*, the court recognized that where an agent was a previously separate economic unit but was "hired for the specific purpose of engaging in a course of anticompetitive conduct and did so, aware of that purpose, which they materially aided in accomplishing,"<sup>87</sup> the relationship would survive *Copperweld* and could sustain a violation of the Sherman Act. This holding is consistent with that of the Supreme Court in *Albrecht v. Herald Co.*<sup>88</sup> In *Albrecht* the defendant hired an agent to solicit newspaper customers to switch delivery methods away from the plaintiff. The Supreme Court found a conspiracy in violation of Section 1, noting that while the agent was undoubtedly acting to earn a fee, it was aware of the aim of the defendant. Thus, the fact that a conspirator participates in an anticompetitive campaign and "materially aids the accomplishment" of his co-conspirator's plan, with knowledge of the purpose, is enough to establish a conspiracy in violation of Section 1.<sup>89</sup>

Indivior argues that there is no actionable conspiracy since MonoSol was not a competitor of Indivior and had no independent reason to harm competition. Indivior claims that the Court must focus on the diminution of competition that would otherwise exist but-for the conspiracy. In fact, that is exactly what Plaintiffs have done—pled facts to show that the

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<sup>86</sup> *Pink Supply Corp. v. Hiebert, Inc.*, 788 F.2d 1313 (8th Cir. 1986).

<sup>87</sup> *Id.* at 1319.

<sup>88</sup> *Albrecht v. Herald Co.*, 390 U.S. 145 (1968).

<sup>89</sup> *Int'l Travel Arrangers, Inc. v. Western Airlines, Inc.*, 623 F.2d 1255, 1266 (8th Cir. 1980).

conspiracy diminished competition in the co-formulated buprenorphine/naloxone market. Adopting Indivior's argument would be illogical and inconsistent with other analyses of conspiracies. Courts are frequently concerned with distinguishing "parallel conduct" from actual conspiracies.<sup>90</sup> Thus, when actors who each have independent reasons to harm competition are alleged to be part of a conspiracy, courts require something more—"evidence that tends to exclude the possibility of independent action."<sup>91</sup> In *Gordon v. Lewiston*, the Court held that it could not infer the existence of a conspiracy because there was no evidence to exclude the possibility that the parties acted independently in undertaking their alleged anticompetitive actions.<sup>92</sup> The parallel conduct analysis defeats Indivior's argument that co-conspirators must be market competitors with an independent interest in the same anticompetitive conduct in order to legally conspire. It is well-established case law that conspiracy claims are properly alleged against non-competitors. Specifically declining to limit conspiracy to horizontal competitors, the Third Circuit stated that doing so would fail to "recognize the difference between motive and objective and would dramatically alter the antitrust landscape in a manner unjustified by either precedent or policy considerations."<sup>93</sup>

Indivior's arguments that it could not conspire with MonoSol based upon its status as a licensee of MonoSol's patent also fails. In the scant cases with such holdings, the entirety of the anticompetitive conduct at issue surrounded the actual use or abuse of the patent.<sup>94</sup> Here, Plaintiffs have described an entire scheme of anticompetitive conduct unrelated to the exercise of

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<sup>90</sup> *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253 (1968).

<sup>91</sup> *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 208 (3d Cir. 2005) (citing *Big Apple BMW Inc. v. BMW of North America, Inc.*, 974 F.2d 1358, 1364, (3d Cir. 1992); *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984)).

<sup>92</sup> *Gordon*, 423 F.3d at 209.

<sup>93</sup> *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 212 (3d Cir. 1992).

<sup>94</sup> *Shionogi Pharma. Inc., v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499 (D. Del. May 26, 2011); *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428 (N.D. Ca. 1992).

the patent. As such, Indivior's status as a licensee of MonoSol's patent has no bearing on the pair's ability to conspire to engage in anticompetitive conduct through other unrelated means.

Despite Indivior's efforts to obfuscate its relationship with MonoSol in order to avoid Section 1 liability, the two companies are not related in any manner contemplated by *Copperweld* or *Siegel*. Indivior and MonoSol are two wholly separate companies who joined together specifically to carry out the purposes of their conspiracy. Neither *Copperweld* nor *Siegel*, nor any other case cited by Indivior, protect two separate legal entities that come together in a joint venture intended to have anticompetitive effects, through a course of conduct which has been sufficiently factually alleged by the Plaintiffs in the FAC.

**D. Indivior's claim that its development of a new product is procompetitive is not grounds for dismissal, but requires development of a factual record.**

Indivior's claims that its introduction of a new product is protected as a procompetitive innovation does not provide a basis for dismissal, and would simply be part of the burden-shifting framework under *Microsoft* after a full development of the record. Plaintiffs wholly dispute the "innovative" nature or alleged advantages of Suboxone Film (and have alleged the opposite in the FAC), but even if it were innovative, Indivior cannot rest on that claim as an absolute defense to antitrust liability. "Changes in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly."<sup>95</sup>

Even if Indivior can show that its design change is beneficial, the Plaintiffs' allegations of other associated anticompetitive conduct can give rise to a violation under Section 2.<sup>96</sup> Assuming that product innovation generally benefits consumers, courts "look for evidence of 'exclusionary or anticompetitive effects' in order to 'distinguish between conduct that defeats a competitor because of efficiency and customer satisfaction' and conduct that impedes

<sup>95</sup> *Allied Ortho. Appliances, Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 998 (9th Cir. 2009).

<sup>96</sup> *Tyco*, 592 F.3d at 998-99, *Doryx*, 838 F.3d at 440.

competition through means other than competition on the merits.”<sup>97</sup> As stated by the *Namenda* court, “product redesign is anticompetitive when it coerces consumers and impedes competition,”<sup>98</sup> because coercion destroys the “free choice of consumers” that normally operates in a market to determine the relative superiority of products.<sup>99</sup> In assessing the anticompetitive effects of product redesign, an examination of *all* anticompetitive actions alleged through a course of conduct analysis is appropriate.<sup>100</sup> Plaintiff States have adequately alleged facts demonstrating that Indivior’s anticompetitive actions destroyed consumers’ free choice. As such, even an innovative product redesign (which Plaintiffs dispute) can be anticompetitive, as “judicial deference to product innovation...does not mean that a monopolist’s product design decisions are per se lawful.”<sup>101</sup> At the very least, this is a question that can only be resolved after full discovery.

**E. Plaintiffs have adequately pled facts supporting allegations of delay.**

**1. Delay through the REMS process is simply one part of Indivior’s anticompetitive scheme.**

Courts are clear that when a plaintiff pleads multiple actions constituting anticompetitive conduct, those actions should be examined for their overall combined effect, rather than considering each aspect in isolation. While a “duty to deal” with its competitors may not have been imposed upon Indivior, Plaintiffs’ FAC does not allege that Indivior’s failure to deal with the generic manufacturers resulted in additional delay. Instead, the States outline facts showing that Indivior *feigned* cooperation with the generics in order to induce the generic manufacturer’s reliance on their eventual cooperation, which never came. This deceptive behavior caused

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<sup>97</sup> *Namenda*, 787 F.3d at 652 (citing *Trans Sport Inc. v. Starter Sportswear, Inc.*, 964 F.2d 186, 188-89 (2d Cir. 1992); *U.S. Football League v. Nat’l Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988)).

<sup>98</sup> *Id.* at 652 (internal citations omitted).

<sup>99</sup> *Id.* at 655.

<sup>100</sup> *Id.* at 654.

<sup>101</sup> *Microsoft*, 253 F.3d at 65.

delays to the generic's REMS process which, combined with the other conduct described in the FAC, comprises part of Indivior's anticompetitive conduct. Since antitrust plaintiffs are permitted to "claim acts as a group have an anticompetitive effect even if the acts taken separately do not,"<sup>102</sup> it is of no consequence that Indivior's actual refusal to deal during the REMS process, if taken alone, may not amount to illegal anticompetitive conduct. The States, like Amneal, have pled that conduct as part of an overarching scheme.

**2. *Apotex* does not defeat Plaintiffs' delay claims with respect to the citizen petition.**

While Indivior argues that the recent ruling in *Apotex*<sup>103</sup> should alter this Court's prior analysis of the citizen petition-related claims of the private class, its reliance on *Apotex* is misplaced. In fact, the *Apotex* opinion itself distinguishes its facts from those at issue here. Most significantly, *Apotex* staked its claim solely on the fact that the FDA's denial of the citizen petition and its approval of *Apotex*'s ANDA were simultaneous. The court indicated that the concurrence of the two decisions alone could not be used to infer a delay due to the citizen petition. Plaintiffs do not rely solely on the timing of the denial of the citizen petition and the approval of any ANDA, nor did this Court so rely in its prior opinions.<sup>104</sup>

Specifically, both this Court and the *Apotex* court cited the many indicia that Indivior's citizen petition was objectively baseless, including (1) the fact that the FDA acknowledged that it could not grant much of the requested relief; (2) the fact that petitioner requested that the FDA investigate why Suboxone Tablets had been withdrawn from the market, yet was still selling the Tablets at that time; and (3) the fact that the FDA itself referred Indivior's conduct to the FTC for antitrust scrutiny.<sup>105</sup> In addition to these factors, the FAC makes additional factual

<sup>102</sup> *Abbott Labs*, 432 F. Supp.2d at 428.

<sup>103</sup> *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51 (2nd Cir. 2016).

<sup>104</sup> Class Plaintiffs Opinion at 31-32; Amneal Opinion at 19-20.

<sup>105</sup> *Apotex*, 823 F.3d at 61-62 (citing *In Re Suboxone Antitrust Litig.*, 64 F. Supp. 3d at 698-691).

allegations of specific intent that demonstrate that the citizen petition was, in fact, a sham meant to delay generic entry.<sup>106</sup> Nothing in *Apotex* mandates a finding different than those already issued by this Court on this very same issue.

### **3. Defendant's proposed time frame defenses are inappropriate.**

Plaintiff States have adequately pled facts showing that Defendant engaged in multiple violations of the Sherman Act. When a monopolist engages in anticompetitive behavior, the effects on the market may last beyond the scope of the antitrust conduct. As explained in a leading treatise,

“A set of strategically planned exclusive dealing contracts may slow the rival's expansion by requiring it to develop alternate outlets for its products or rely at least temporarily on inferior or more expensive outlets. Consumer injury results from the delay that the dominant firm imposes on the smaller rival's growth.”<sup>107</sup>

Thus, any strict reliance on the timing of Defendant's conduct to curtail the period during which anticompetitive effects and antitrust injury may be experienced is inappropriate. Moreover, anticompetitive effects and antitrust injury must be based upon factual findings after discovery is conducted. Dismissing claims for any particular segments of time at the motion to dismiss stage is procedurally improper.

### **F. The state law claims should not be dismissed.**

Indivior argues that each of the 42 Plaintiff States' state law claims rise and fall with their federal counterparts, and relies on arguments made in co-defendant Reckitt Benckiser Healthcare (UK) Ltd.'s brief. As more fully explained in the States' opposition to that defendant's motion, and incorporated here by reference, Indivior's argument should be rejected. Plaintiffs have sufficiently pled claims for relief under the Sherman Act, and the state law claims are not solely reliant upon the federal claims.

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<sup>106</sup> See FAC ¶ 107.

<sup>107</sup> Herbert Hovenkamp, *Antitrust Law* ¶ 1802c, at 64 (2d ed. 2002).

## CONCLUSION

For the foregoing reasons, Plaintiff States respectfully request that the Court deny Indivior's motion to dismiss.

Respectfully submitted,

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